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By: Jennifer Mahan

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF:

Soos, J.M, et al.

SERIAL NO: Not yet Assigned

FILED: Concurrent Herewith

FOR: ORALLY-ADMINISTERED INTERFERON-  
TAU COMPOSITIONS AND METHODS

EXAMINER: Unknown

ART UNIT: Unknown

**PRELIMINARY AMENDMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to calculation of the filing fee and examination of the above-noted application, amend the claims as follows.

In the Claims: Cancel claims 6, 7, and 10-19 without prejudice; replace claims 1-5, and 9 with the following rewritten claims; and add new claims 20-36 as follows:

1. (Amended) In a method of treating a viral disease in a mammal responsive to treatment by ovine interferon-tau (IFN<sub>τ</sub>), an improvement comprising orally administering a therapeutically-effective amount of bovine IFN<sub>τ</sub> through oral ingestion.

2. (Amended) The method of claim 1, wherein IFN<sub>τ</sub> is orally-administered at a dosage of greater than about  $1 \times 10^5$  units per day.

3. (Amended) The method of claim 1, wherein IFN<sub>τ</sub> is orally-administered at a dosage of greater than about  $1 \times 10^6$  units per day.

4. (Amended) The method of claim 1, wherein the bovine IFN<sub>τ</sub> has an amino acid sequence homology of at least about 80% with an ovine IFN<sub>τ</sub> (OvIFN<sub>τ</sub>) amino acid sequence.

5. (Amended) The method of claim 1, wherein said bovine IFN<sub>τ</sub> has a sequence homology of at least about 80% with an ovine IFN<sub>τ</sub> sequence represented as SEQ ID NO:2.

9. (Amended) The method of claim 20, wherein said mammal is a dog.

20. (New) The method of claim 1, wherein the mammal is a domesticated animal.

21. (New) In a method of treating a condition associated with cellular proliferation in a mammal responsive to treatment by ovine interferon-tau (IFN<sub>τ</sub>), an improvement comprising orally administering a therapeutically-effective amount of bovine IFN<sub>τ</sub> through oral ingestion.

22. (New) The method of claim 21, wherein IFN<sub>τ</sub> is orally-administered at a dosage of greater than about  $1 \times 10^5$  units per day.

23. (New) The method of claim 21, wherein IFN<sub>τ</sub> is orally-administered at a dosage of greater than about  $1 \times 10^6$  units per day.

24. (New) The method of claim 21, wherein the bovine IFN<sub>τ</sub> has an amino acid sequence homology of at least about 80% with an

ovine IFN $\tau$  (OvIFN $\tau$ ) amino acid sequence.

25. (New) The method of claim 21, wherein said bovine IFN $\tau$  has a sequence homology of at least about 80% with an ovine IFN $\tau$  sequence represented as SEQ ID NO:2.

26. (New) The method of claim 21, wherein said mammal is a human.

27. (New) The method of claim 21, wherein the mammal is a domesticated animal.

28. (New) The method of claim 27, wherein said mammal is a dog.

29. (New) In a method of treating an inflammatory disease condition in a mammal responsive to treatment by ovine interferon-tau (IFN $\tau$ ), an improvement comprising orally administering a therapeutically-effective amount of bovine IFN $\tau$  through oral ingestion.

30. (New) The method of claim 29, wherein IFN $\tau$  is orally-administered at a dosage of greater than about  $1 \times 10^5$  units per day.

31. (New) The method of claim 29, wherein IFN $\tau$  is orally-administered at a dosage of greater than about  $1 \times 10^6$  units per day.

32. (New) The method of claim 29, wherein the bovine IFN $\tau$  has an amino acid sequence homology of at least about 80% with an ovine IFN $\tau$  (OvIFN $\tau$ ) amino acid sequence.

33. (New) The method of claim 29, wherein said bovine IFN $\tau$  has a sequence homology of at least about 80% with an ovine IFN $\tau$  sequence represented as SEQ ID NO:2.

34. (New) The method of claim 29, wherein said mammal is a human.

35. (New) The method of claim 29, wherein the mammal is a domesticated animal.

36. (New) The method of claim 35, wherein said mammal is a dog.

REMARKS

Entry of the claim amendments and additions prior to examination is respectfully requested. Attached hereto is a marked up version of the changes made to the claims. The attached page is entitled "**Version with Markings to Show Changes Made.**"

I. Amendments

Claim 1 has been amended to describe a method for treating a viral disease in a mammal. Basis for this amendment can be found, for example, on page 9, lines 20-24 and page 28, lines 5-31. Claim 1 is also amended to state that the IFN<sub>τ</sub> is administered through oral ingestion, as described, for example on page 7, line 35 to page 8, line 1. Claim 1 further describes that the IFN<sub>τ</sub> is bovine IFN<sub>τ</sub>, as set forth on page 12, line 31.

Claims 2 and 3 are amended to describe that the IFN<sub>τ</sub> is administered at a dosage of greater than about 1x10<sup>5</sup> (claim 2) and about 1x10<sup>6</sup> (claim 3) units per day. Basis for these amendments can be found on page 31, line 35 to page 32, line 11.

Claims 4 and 5 are amended to recite that the bovine IFN<sub>τ</sub> has an amino acid sequence homology of at least about 80% with ovine IFN<sub>τ</sub> amino acid sequence. Basis for this amendment can be found on page 12, line 31 to page 13, line 4.

Claim 9 is amended to depend from new claim 20, which describes an embodiment where the mammal treated with the IFN<sub>τ</sub> is a domesticated animal. Basis for new claim 20 is on page 29, lines 25-27..

New claim 21 parallels claim 1 for treating a condition associated with cellular proliferation. Basis for treatment of this condition is found, for example, on page 28, line 34 to page 29, line 5 and on page 24, line 35.

Dependent claims 22-28 parallel dependent claims 2-5, 8, 9 and 20, discussed above.


New claim 29 parallels claim 1 for treating an inflammatory disease condition in a mammal, as described, for example, on page 24, line 34.

Dependent claims 30-36 parallel dependent claims 22-28 and 2-5, 8, 9, and 20.

Accordingly, no new matter is added by these amendments.

Respectfully submitted,

Date: 12/21/01

  
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) In a method of treating a viral disease [condition] in a mammal responsive to treatment by ovine interferon-tau ( $\text{IFN}_\tau$ ), an improvement comprising orally administering a therapeutically-effective amount of bovine  $\text{IFN}_\tau$  through oral ingestion.

2. (Amended) The method of claim 1, wherein  $\text{IFN}_\tau$  is orally-administered at a dosage of [between] greater than about  $1 \times 10^5$  [and about  $1 \times 10^8$ ] units per day.

3. (Amended) The method of claim [2] 1, wherein  $\text{IFN}_\tau$  is orally-administered at a dosage of [between] greater than about  $1 \times 10^6$  [and about  $1 \times 10^7$ ] units per day.

4. (Amended) The method of claim 1, wherein the bovine  $\text{IFN}_\tau$  has an amino acid sequence homology of at least about 80% with an [orally-administered  $\text{IFN}_\tau$  is] ovine  $\text{IFN}_\tau$  ( $\text{OvIFN}_\tau$ ) amino acid sequence.

5. (Amended) The method of claim 1, wherein said [ $\text{OvIFN}_\tau$ ] bovine  $\text{IFN}_\tau$  has [the] a sequence homology of at least about 80% with an ovine  $\text{IFN}_\tau$  sequence represented as SEQ ID NO:2.

9. (Amended) The method of claim [1] 20, wherein said mammal is a dog.